

DETAILED ACTION

The Final rejection of 16 October 2008 is hereby vacated, and the following Office action is provided.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 Aug 2008 has been entered.

The drawings received 8/22/2008 have been entered.

Status of the Claims

Claims 1-21 are cancelled. Claims 22-25 are presented for examination on the merits.

Claim Rejections - 35 USC § 103

The rejection under 103 is withdrawn in view of the newly added limitation of lacking a washout period before step A. It is agreed that McMahan teaches away from lacking a washout period, because there is a clear requirement for a two-step washout period prior to initiation of PRA measurement. However, if applicants delete this newly added limitation in response to the new matter rejection *infra*, the 103 rejection would be reinstated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims are drawn to a method of treating a hypertensive subject having a normal to above normal plasma rennin activity level. The claims in question recite a “said method does not include a washout period before step A” (in claims 22 and 23).

Lack of *Ipsis verbis* support

The specification is void of any literal support for the above listed phrases and numbers (and/or ranges). The words “washout” “wash” listed above were searched, and they were not found anywhere in the specification.

Lack of Implicit or Inherent Support

“While there is not in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” See MPEP 2163. Thus support can be furnished implicitly or inherently for a specifically claimed limitation. However, the specification lacks any implicit or inherent support for the above listed claim limitations. As explained *supra*, there is no support for any concepts listed above. For example, no description/definition as to what “washout step” is, no explanation/implication that elimination of thus “washout” step is patentably distinct.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571) 272-0925.

B Shen

Art Unit 1657

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657